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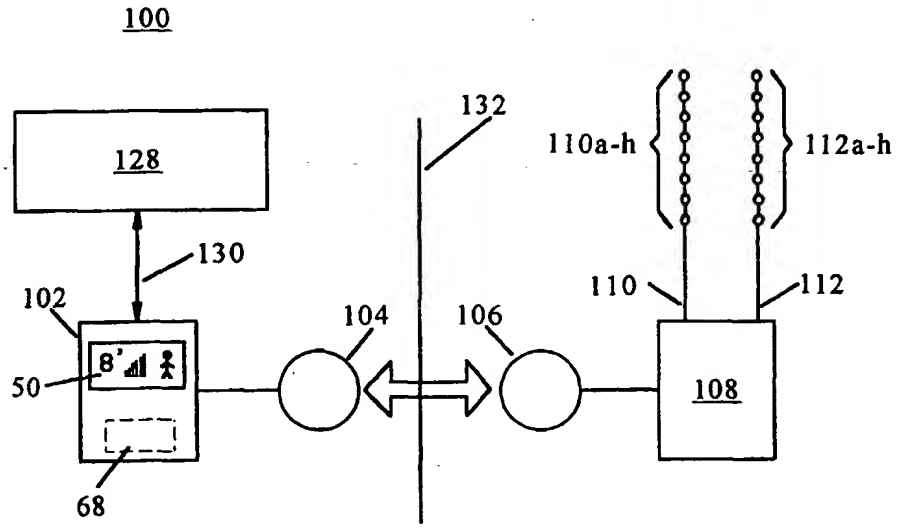
(54) Title: NEUROMODULATION THERAPY SYSTEM




(57) Abstract: A neuromodulation therapy system (100) includes a programmer and a stimulation system. The stimulation system is capable of storing multiple data sets, each data set effecting an independent therapy. The stimulation system includes a display mechanism (50) that can display certain imagery to distinguish visually one therapy from another therapy. A transmitter (102) transmits instructional control signals to an implantable receiver (108).

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# NEUROMODULATION THERAPY SYSTEM

## FIELD OF THE INVENTION

The present invention relates to a system that is capable of storing multiple data sets, which are not otherwise identifiable but for individual execution of such data sets; however, the system includes a display mechanism to display certain visual imagery to enable the functionality of each data sets to be distinguished.

## BACKGROUND OF THE INVENTION

Application of specific electrical fields to spinal nerve roots, the spinal cord, and/or other nerve bundles for the purpose of chronic pain management has been actively practiced since the 1960s. While a precise understanding of the interaction between the applied electrical energy and the nervous tissue is not fully appreciated, it is known that application of an electrical field to spinal nervous tissue (i.e., spinal nerve roots and spinal cord bundles) can effectively interfere with the transmission of certain pain signals through such nervous tissue. More specifically, applying particularized electrical pulses to spinal nervous tissue that corresponds to regions of the body afflicted with chronic pain can induce paresthesia, or a subjective sensation of numbness or tingling, in the pain-afflicted regions. Depending on the individual patient, paresthesia can effectively "mask" certain pain sensations to the brain.

The above description uses the term "particularized" to denote that the applied electrical energy is intended to be focused on the specific spinal nervous tissue associated with the afflicted bodily regions. Care should be taken to avoid over stimulating the targeted nervous tissue, as over stimulation could lead to paresthesia being perceived in non-afflicted regions or, alternatively, feelings of discomfort.

As a first step to delivering effective electrical energy to targeted nervous tissue, the source of the electrical energy must be positioned proximate to such nervous tissue. Electrical energy is commonly delivered through conductive electrodes positioned external to a patient's dura layer, a structure that surrounds the spinal cord. Electrodes are carried by two

primary vehicles: the percutaneous catheter and the laminotomy lead. Percutaneous catheters and laminotomy leads will be collectively referred to as "stimulation leads."

Percutaneous catheters, or percutaneous leads, commonly have two or more electrodes (for example, two, four, and eight) and are positioned above the dura layer through the use of a Touhy-like needle that passes through the skin, between desired vertebrae, and opens above the dura layer. Laminotomy leads have a thin paddle configuration and typically possess a plurality of electrodes (for example, two, four, eight, or sixteen) arranged in one or more columns. Surgical intervention is required for implanting laminotomy leads. In particular, a partial laminectomy is required, which involves the resection and removal of certain vertebral tissue to allow both access to the dura and proper positioning of the laminotomy lead.

Assuming that physical placement of the electrical energy source can be achieved, specific "selection" of the targeted nervous tissue from an encompassing tissue bundle is achieved through refinement of the delivered electrical energy. To this end, the delivered electrical energy is defined by an electrode configuration and an electric pulse waveform, or collectively a "stimulation setting."

The overall form of the delivered electrical energy is defined by the polarity of each electrode of the stimulation lead. With modern stimulation systems, each electrode can assume a positive polarity (an anode), a negative polarity (a cathode), or an off-state. The collective definition of the polarities of each electrode of a stimulation lead is described as an "electrode configuration."

The electric pulse waveform defines the nature of the signal delivered through the active electrodes. Of course, an electric pulse waveform is defined by a plurality of variables, including: pulse width (μs) (i.e., the duration in which the pulse is in a high state), frequency (Hz), amplitude (V), and sometimes phase (i.e., mono-phasic or bi-phasic). For purposes of description, a collection of these variables to define a single waveform will be referred to as a "treatment parameter set."

Identifying an optimum stimulation setting——one that masks a maximum quantity of pain with minimum over stimulation——can be time consuming and difficult. In particular, not even considering the endless combinations that can be effected by modifying the variables of a treatment parameter set, an eight-electrode stimulation lead offers 6,050 possible electrode combinations.

As may be understood from the above description, a single stimulation setting corresponds to a single treatment parameter set and a single electrode configuration. Consequently, each stimulation setting typically addresses only a single localized region of the body. If a patient experiences complex pain (i.e., pain that extends across multiple or varied regions of the body), then multiple stimulation settings may be required to address such pain. Further yet, different stimulation settings may be required for different times of the day or for different activities within the day, whereas changes in body position (e.g., lying down, sitting, standing) may impair or alter the effectiveness of any one stimulation setting.

FIGURE 1 illustrates a modern, radio frequency (RF) stimulation system 1000. In particular, the system 1000 includes an external transmitter 1002 that is connected to an antenna 1004. Internally, a receiver 1008 is connected to at least one stimulation lead 1010 (and 1012), which in this instance is illustrated having eight electrodes 1010a-h (and 1012a-h for stimulation lead 1012). The receiver 1008 communicates, via an antenna 1006, with the transmitter 1002 through the skin 1032 of a patient.

Stimulation settings are stored within a memory of the transmitter 1002. Stimulation settings can be programmed into the transmitter 1002 using transmitter-based controls (not shown) or using a computer 1028 (e.g., U.S. Patent No. 5,938,690 to Law et al.) through a removable connection 1030. Operatively, stimulation settings are imposed on a RF carrier signal and passed to the receiver 1008 through the skin 1032 to effect stimulation through electrodes 1010a-h and 1012a-h.

The system 1000 allows the storage and application of 1-24 stimulation settings. Each stimulation setting is numerically represented (i.e., "1", "2", "3", etc.) based on an order

of input into the transmitter 1002. The transmitter 1002 executes all stored stimulation settings sequentially, based on the settings' respective numerical representations. The execution of "adjacent" stimulation settings is made within a fixed time interval, such interval being of such a duration that switching between adjacent stimulation settings is largely imperceivable to the patient.

To this end, the conventional system would enable up to 24 different pain areas to be addressed. However, short of re-programming the stored stimulation settings, this system does not readily allow changes in stimulation settings for changes in activities or patient posture. Moreover, with each stimulation setting being simply represented by an alphanumeric representation, a patient or practitioner must maintain a separate log that correlates each stimulation setting with its stimulation effect. Otherwise, the patient would be required to execute each stored stimulation setting to appreciate its consequence.

Accordingly, a need exists for a stimulation system that provides a user substantive information regarding the effects or intended application of a stored stimulation setting.

A further need exists for a stimulation system that allows stored stimulation settings to be both readily and arbitrarily grouped, whereas each stimulation setting of a group is directed to addressing a common condition, and multiple groups are available for execution.

## SUMMARY OF THE INVENTION

An object of the present invention is to overcome the known limitations of current neuromodulation systems described above.

Another object of the present invention is to provide a display mechanism for a user-portion of a neuromodulation system that conveys graphical information to a user regarding the intended effect of a stimulation setting.

To this end, one aspect of the present invention is directed to a tissue stimulation system having a transmitter, a receiver for implantation within a patient, and at least one

multi-electrode, implantable stimulation lead. The stimulation lead is electrically connectable to the receiver. The transmitter is adapted to transmit stimulation data to the receiver, which effects delivery of electrical energy through the connected stimulation lead. Importantly, the delivered electrical energy is defined by stimulation setting(s).

Unlike known systems, the system of this aspect includes a memory adapted to store at least two programs, each program including a plurality of stimulation settings, a selector, and a controller. The selector operatively effects a selection of a stored program. The controller executes any selected programs, such involving the conversion of a stimulation setting of the selected program to stimulation data for transmission to the receiver.

For a neuromodulation system having a memory to store a plurality of independent instructions to effect an equal number of stimulation profiles, another aspect of the present invention is directed to a method for providing an identifier to enable a visual recognition of a functionality of each instruction. The steps for such provision include creating an instruction data file, which includes a plurality of variables that operatively defines a therapeutic application, to effect a stimulation profile when executed; and generating a graphical anatomical representation that effectively depicts a perceived stimulation profile. From this action, the anatomical representation is assessed so to generate a representative graphical image. With such image, the instruction data file is modified to include data corresponding to such representative graphical image.

Other objects and advantages of the present invention will be apparent to those of ordinary skill in the art having reference to the following Specification together with the drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings in which like reference numerals and letters indicate corresponding elements throughout the several view, if applicable:

FIGURE 1 is a schematic representation of a conventional radio-frequency neuromodulation system;

FIGURE 2 is a schematic representation of a radio-frequency neuromodulation system in accordance with the present invention;

FIGURE 3 illustrates a radio-frequency transmitter for use in the system of FIGURE 2;

FIGURE 4 schematically illustrates both a program data file and a stimulation setting data file operatively stored within the transmitter of FIGURE 3;

FIGURE 5 illustrates one possible display arrangement presentable on a display of the transmitter of FIGURE 3;

FIGURE 6 illustrates another possible display arrangement presentable on the display of the transmitter of FIGURE 3;

FIGURES 7A through 7D illustrate various display arrangements presentable on the display of the transmitter of FIGURE 3 in a program selection mode;

FIGURE 8 schematically illustrates a database structure employed by software subject to execution by a computer of the system of FIGURE 2;

FIGURES 9A through 9E illustrate various screen shots from software (subject to execution by a computer of the system of FIGURE 2) and related transmitter displays, that operatively relate to the identification, setting, selection, and downloading of one or stimulation programs;

FIGURE 10 illustrates anterior and posterior views of a bodily image graphic displayed by software subject to execution by a computer of the system of FIGURE 2;

FIGURE 11 illustrates a composite bodily graphic presentable on the display of the transmitter of FIGURE 3, which is visually formed from data of the anterior and posterior views of the bodily image graphic of FIGURE 10;

FIGURE 12 partially illustrates a conversion table that includes data that establishes a graphical relationship among the display of the transmitter of FIGURE 3, the composite

bodily graphic of FIGURE 11, and the anterior view of the bodily image graphic of FIGURE 10;

FIGURE 13 partially illustrates a conversion table that includes data that establishes a graphical relationship among the display of the transmitter of FIGURE 3, the composite bodily graphic of FIGURE 11, and the posterior view of the bodily image graphic of FIGURE 10;

FIGURE 14 is a flow chart algorithm for the storage of image-related data that comprises the anterior and posterior views of the bodily image graphic of FIGURE 10;

FIGURE 15 is a flow chart algorithm for graphical image conversion from the anterior and posterior views of the bodily image graphic of FIGURE 10 to the composite bodily graphic of FIGURE 11; and

FIGURES 16A and 16B illustrate alternative methods of delivering multiple stimulation settings.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Various embodiments, including preferred embodiments, will now be described in detail below with reference to the drawings.

FIGURE 2 illustrates one embodiment of a system in accordance with the present invention. The system 100 includes an external transmitter 102 that is connected to an antenna 104. Internally, a receiver 108 is connected to at least one stimulation lead 110 (and 112), which in this instance is illustrated having eight electrodes 110a-h (and 112a-h for stimulation lead 112). The receiver 108 communicates, via an antenna 106, with the transmitter 102 through the skin 120 of a patient. While the receiver 108 can include an internalized power source, it is more likely that the receiver 108 is powered by the carrier wave transmitted by the transmitter 102.

The computer 116 is a general-purpose computer that includes executable software. The computer 116 is capable of receiving input via its display (i.e., touch screen) or through a mouse or a stylus (not shown). While not critical to the invention, the computer 128

preferably operates in a Windows™-based environment. The computer 128 should include, or otherwise be connectable to, a display (or other output device) having a sufficient resolution so as to clearly present the visual information required by the present invention, such information being discussed in greater detail below.

The computer 128 is connectable to the transmitter 102 through a cable 130. In particular, it is preferable that the cables 130 extend between a standard RS232 serial port of the computer 128 and a serial connector (not shown) on the transmitter 102. Alternatively, the computer 128 and the transmitter 102 could be "connected" using an infrared transmission, a radio-frequency transmission, or an ultrasonic transmission.

The communication protocol used between the computer 128 and the transmitter 102 is preferably conventional, using traditional message blocks. Such message blocks incorporating message identification, type, data, checksum, and length fields. Component responses to data transmissions are likewise traditional, i.e., using ACK and NACK signals.

FIGURE 3 illustrates one embodiment of the transmitter 102. The transmitter includes a display 50. In a preferred embodiment, the display 50 has a resolution that allows alphanumeric and limited graphics data to be displayed, whether in monochrome or in color. In a preferred embodiment, the display 50 is a 100 column x 32 row, monochrome LCD. While the specific controls are not necessarily critical to the invention, such will be at least mentioned here for reference.

User controls 52 and 54 function to respectively decrease and increase certain definable variables, e.g., stimulation amplitude. User control 56 functions to "cancel" an input or screen selection. User controls 58 and 60 are scroll controls, to enable a user to scroll through various presented options. User control 62 is an "enter" key, wherein inputs or options are selectable through actuation of user control 62. User control 64 is a "balance" key, which enables individual amplitude adjustment for each available stimulation setting of a program, its use will be discussed further below. Finally, user control 66 is a power switch.

The transmitter 102 functions to receive and store one or more stimulation settings. Stimulation settings can be entered or modified through the user controls 52, 54, and 58-64 and/or through the connected computer 128. Stimulation settings are stored in a non-volatile memory 68. Memory 68 requires a capacity sufficient to store a prescribed number of programs, and each program can include multiple stimulation settings. In a preferred embodiment, the transmitter 102 can operatively maintain at least two programs, each program including at least two stimulation settings. In a more preferred embodiment, the transmitter 102 can operatively maintain more than ten programs, each program maintaining no more than ten stimulation settings. In a most preferred embodiment, the transmitter 102 can operatively maintain twenty-four programs, and each program can maintains eight stimulation settings.

FIGURE 4 illustrates a program data file as maintained in the transmitter 102, and more particularly, within the memory 68. The program data file includes space for a program number, a quantity of stimulation settings within the program, composite graphic data, and a maximum number of stimulation setting files. Each stimulation setting data file includes space for a program number, a stimulation setting number, a frequency value, a pulse width value, an electrode configuration (to define the state for each of the connected electrodes 110a-h and 112a-h), minimum and maximum amplitude limitations, and graphics data.

Operatively, for an active program, a microprocessor (not shown) within the transmitter 102 reads the memory 68 and extracts the program-specific data. The program-specific data is displayed in the display 50. An example of such a display is shown in FIGURE 5.

In reference to FIGURE 5, region 25 indicates that program no. 8 is active, and that this program includes four stimulation settings. Region 26 depicts an overall-amplitude control adapted to control commonly an amplitude value for all stimulation settings of the active program. The overall-amplitude control is managed using user controls 52 and 54. In region 27, a battery life indicator is provided. While the battery life indicator is shown reflecting a specific time format (i.e., hours : minutes), such indicator could also display a

relative time remaining using a variably filled battery form. Lastly, region 28 includes a composite graphic, which is formed from graphics data contributed from each of the stimulation settings of the program. The "composite" bodily graphic readily conveys to a user which regions of the patient's body are addressed by the current program. In particular reference to the illustrated graphic of region 28, program no. 8 effects stimulation in the right arm 28a, the left arm 28b, the right leg 28c, and the left leg 28d.

Of note, while FIGURE 5 illustrates an overall-amplitude control, the transmitter 102 also allows the amplitude of each stimulation setting to be individually modified. Accordingly, delivered energy is governed by (i) individual amplitude settings, which are confined between minimum and maximum amplitude limits as defined in the respective stimulation setting data files and (ii) the overall-amplitude control. In regard to the latter, if the overall-amplitude control is set, for example, at 30% of maximum, each stimulation setting will realize only 30% of its set amplitude. FIGURE 6 illustrates an example display that enables the individual adjustment of each of the stimulation settings of the program illustrated in FIGURE 5.

In reference to FIGURE 6, arrow 30 indicates which stimulation setting amplitude is subject to modification. Control of arrow 30 is performed by user controls 58 and 60. Selection of a stimulation setting is effected by actuation of user control 62. Region 29 reflects respective "slider" controls for each stimulation setting. The individual minimum value (i.e., lower position of each slider) and maximum value (i.e., upper position of each slider) is dictated by the provided minimum and maximum amplitude limits, which (as stated above) are set within the individual stimulation setting files. Gradation fineness along each slider is a function of the differential between the maximum and minimum amplitude limits.

The display of region 31 is a function of the position of the arrow 30. In particular, the displayed graphic reflects the bodily region addressed by the selected stimulation setting. In this instance, the right arm 28a is shown (of note, this right arm representation is also a part of the composite graphic displayed in FIGURE 5).

For this particular embodiment, the display of FIGURE 6 is accessed by actuation of user control 64. For safety purposes, it is preferred that modification of individual amplitude settings cannot occur unless the overall-amplitude is set to a low percentage value, e.g., 0%.

Focusing on the actual delivery of stimulation, for each stimulation setting, the microprocessor reads such stimulation setting from the active program, effects a multiplexing of the substantive data, or treatment parameter set (i.e., frequency, pulse width, phase, and electrode configuration) and a separately-stored, related amplitude value, and drives the delivery of the multiplexed data to a modulator (not shown) for preparation and combination with a generated RF carrier wave. The data-supporting carrying carrier wave is then passed to the antenna 104, which forwards the integrated stimulation setting (i.e., electrode configuration and waveform definitional variables) and carrier wave, which represents a source of power for the receiver 108, to the antenna 106 and the connected receiver 108.

For a program having multiple stimulation settings, the microprocessor automatically cycles through each of the stimulation settings, executing each setting in a manner consistent with the above description. The microprocessor controls the time that any one stimulation setting is executed. For example, the microprocessor could define a specific period (e.g., 10 milliseconds), a period based on a frequency of the stimulation setting (e.g., two cycles, three cycles), or a combination of both (e.g., at least two cycles but not less than 10 milliseconds). Consistent with known systems, it is preferable that any time between executed stimulation settings be negligible so that a patient cannot readily perceive a transition between adjacent stimulation settings. As a further alternative, the microprocessor could execute one stimulation setting per pulse, thus creating a truly "seamless" therapy application. These alternatives are illustrated in FIGURES 16A AND 16B.

Multiple programs, which include one or more stimulation settings, can be used to address the shortcomings of the current art described earlier. Specifically, the user can establish different programs to address different activities as well as different postures. When the transmitter 102 has received multiple programs, the user actuates a user control of the transmitter 102 (e.g., the user controls 58 or 60) to access a program selection mode

(indicated by a "P" in the lower left-hand corner of the display 50). Upon actuation of the user control 62, controls 58 and 60 are then used to scroll through the possible stored programs (FIGURES 7A-7D). Selection of any one program is effected through actuation of the user control 62. Of note, the illustrated graphics of the regions 28 of FIGURES 7A-7D reflect the different stimulation option available: left and right legs (PROGRAM 2); upper torso (PROGRAM 3); left and right arms and lower back (PROGRAM 4); and left and right arms and left and right legs (PROGRAM 5).

While the above discussion has focused on the user-portion of the present invention, the following discussion will be particularly directed to the software that is executed by the computer 128. In a general sense, the software offers the following features:

- patient entry and identification;
- real-time definition and testing of stimulation parameters;
- documentation of tested stimulation results via graphical stimulation map(s);
- storage of tested parameters, including graphical stimulation map(s);
- review and selection of tests results for therapy definition;
- conversion of graphical stimulation map(s) for use by the user device (e.g., transmitter 102); and
- download of defined therapies to the user device.

Additional features of the software include those also identified in co-pending United States patent application no. --/---,---, filed June 5, 2000, such disclosure being incorporated by reference herein.

Of the features above, "patient entry and identification" concerns the interface and record-keeping processes to manage the records stored within the computer 128. Reference is hereby made to FIGURE 8, which illustrates the database structure used by the software. As can be seen in this figure, each record is indexed by a patient identification (e.g., a patient name), and in many instances, the patient's physician for verification. The PATIENTS and PHYSN tables 70 and 72 cooperate to maintain various, common identification and personal

information, including: a patient name, physician, address, date of birth, etc. The means used to obtain this information, and even the information itself, is not essential to the present invention, excepting its role as a basis to establish an effective relational database.

In continued reference to FIGURE 8, the lines and arrows connecting the various tables illustrate a preferred structure that establishes relationships and avoids duplication of data. Relationships between database tables are designated by a "*". Moreover, as a further example of this reduction in storage overhead, the TESTRES table 80 is used for both storage of tests and program definition. When considering the relational dependency of the STIMMAP table 82, there is need for only one stimulation image for every test (i.e., stimulation setting). While the present system could provide for multiple images (or the data representative of multiple images) to be recorded for each stimulation setting, at least this embodiment does not incorporate such variation. Thus, there is a one-to-one correspondence between each test result entry and the STIMMAP table 82.

**Real-Time Definition And Testing Of Stimulation Parameters**

In explaining the process of real-time definition and testing of stimulation parameters, reference will be made to the screen shot of the software reproduced in FIGURE 9A. The illustrated screen is the "stimulation parameter adjustment and testing screen." To define a stimulation parameter, the following steps are followed:

Step #1: With an amplitude set to O V (Field 206), a practitioner defines an electrode configuration (Field 200), a frequency value (Field 202), and a pulse width value (Field 204).

Step #2: The amplitude "slider" (Field 205) is adjusted, and a patient response is recorded at the amplitude where stimulation is first perceived using screen button 208a.

Step #3: The practitioner highlights all regions of the stimulation image (Region 210) that correspond to the actual perceived stimulation experienced by the patient. Of note, the stimulation diagram initially begins as only a bodily outline having a plurality of demarcated, non-highlighted regions (FIGURE 10).

Step #4: The amplitude slider (Field 205) is again adjusted, and a patient response is recorded at the amplitude where bilateral stimulation is first perceived using screen button 208b.

Step #5: The practitioner highlights all regions of the stimulation image (Region 210) that correspond to the perceived feeling of the patient at such bilateral perception. Highlighting regions previously highlighted in Step #3 will result in such regions being updated with a bilateral-related value.

Step #6: The amplitude slider (Field 205) is again adjusted, and a patient response is recorded at the amplitude where maximum stimulation is first perceived using screen button 208c. Maximum stimulation is usually determined by the invocation of involuntary muscle reaction or other conditions that are equally undesirable.

Step #7: The practitioner highlights all regions of the stimulation image (Region 210) that correspond to the perceived feeling of the patient at motor perception. Highlighting regions previously highlighted in Steps #3 or Steps #5 will result in such regions being updated with a motor-related value.

Step #8: The defined stimulation parameters and related stimulation image is saved by actuating the "log setting" screen button (Region 212). The corresponding treatment parameter set is stored in portion 80 of TESTRES table 78 (Step S102 of FIGURE 14, discussed hereinbelow), and data representative of the stimulation image are stored in portions 86 and 88 of STIMMAP table 82 (Steps S108 and S114 of FIGURE 14, discussed hereinbelow). The stimulation image is preferably stored on a region-by-region basis and can be represented by binary data or an analog data. While not preferable, the image as a whole (i.e., a bitmap) could be stored.

For each region of pain or variation in posture that may require a different stimulation setting, Steps 1-8 are repeated to obtain the necessary number of treatment parameter sets.

From the perception, bilateral, and motor amplitude values entered in the above steps, the software defines a minimum amplitude value and a maximum amplitude value for the

corresponding stimulation setting. As shown in FIGURE 4, these values are stored in each stimulation setting data file. While not within the scope of this disclosure, the software can further use the perception, bilateral, and motor amplitude values to calculate an initial stimulation amplitude, or a comfort amplitude. As but one example, the comfort amplitude is equivalent to the perception amplitude plus an incremental value, such incremental value being based on the bilateral and the motor amplitude values (e.g., 60% of a difference between the motor amplitude value and the bilateral value). The comfort amplitude can be downloaded and stored in association with a corresponding treatment parameter set.

Further, as may be appreciated, the individual and composite stimulation graphics displayed on the display 50 of the transmitter 102 (see FIGURES 5, 6, and 7A-D) are derived from the stimulation images generated in the Steps #3, #5, and #7 described above (e.g., 40 → 40' and 42 → 42' in FIGURES 10 and 11). As the image of the computer-based images possess significantly greater resolution, however, these images must be reduced to correspond to the display 50 of the transmitter 102. However, as the stimulation image to be displayed on the transmitter 102 is intended to convey valuable information to a user concerning the effect of a stored, corresponding stimulation setting (i.e., an accurate representation of the stimulation images from the definition and testing session(s)), it is important that the conversion process not vitiate the significance of the data being converted.

For a description of the conversion process, reference will be made to FIGURES 9A and 10-15.

FIGURES 12 and 13 illustrate graphic conversion tables that provide a "road map" to effecting a graphical conversion from the graphical platform of the computer 128 to the graphical platform of the transmitter 102. The content of the conversion tables is a direct function of the display 50 and its display matrix.

As background for some of the numerical entries in the tables of FIGURES 12 and 13, the display 50 used in this example requires input command signals of a 1 byte form. Each byte represents a vertical column of eight pixels. Either a pixel is "on" or "off" based on the

defining bits of each byte. Conventionally, "0" represents an off-state, and "1" represents an on-state. Further to the characteristics of the display 50, which is said to a 100 column by 32 row field for purposes of this description, addressing a particular column is made by particular reference to 1-100; however, addressing a particular row is achieved through "page" references. For example, "page 1" is the top page, or rows 1-8 of the display 50; "page 2" represents rows 9-16 of the display 50; "page 3" represents rows 17-24 of the display 50; and "page 4" is the bottom page, or rows 25-32 of the display 50. Moreover, the display related transfer protocol requires that for each "page," two image-forming instructions must be transferred——one instruction for the right side of the image, and one instruction for the left side of the image.

In view of these protocol-established boundaries of this exemplary embodiment, the following meanings can be imparted to the headings of the tables of FIGURES 11 and 12. FIGURE 12 concerns ANTERIOR image regions, and FIGURE 13 concerns POSTERIOR image regions.

Column 1: Region numbers that directly correspond to the regions of the stimulation images displayed on the computer 128 (FIGURE 10).

Column 2: Anatomical description of each region.

Column 3: A value (0-3) that corresponds to the LCD positional "page" reference, described hereinabove.

Column 4: A value (1-20) that corresponds to a pixel column of the left portion of the image. When executed by the transmitter 102, an offset is applied to the value to allow the image to be properly positioned within the display 50.

Column 5: Decimal equivalent of the hexadecimal byte used to define a pixel representation for the left portion of the image being converted.

Column 6: A value (1-20) that corresponds to a pixel column of the right portion of the image. When executed by the transmitter 102, an offset is applied to the value to allow the image to be properly positioned within the display 50.

Column 7: Decimal equivalent of the hexadecimal byte used to define a pixel representation for the right portion of the image being converted.

Each conversion table sets forth an entry for each of the regions shown in the stimulation images (see FIGURES 10, 12, and 13). Notably, where left regions (and right regions) are converted and do not share pixel boundaries with another region, the Column 2 bit mask is set to zero. This allows the relevant left areas (and relevant right areas) to be masked appropriately without adding additional complexity to either the conversion tables or the controlling software. As may also be observed from the conversion tables, there is no provision for the conversion and transfer of the bodily representation displayed on the display 50. To avoid unnecessary data transfer, preferably such bodily representation is maintained in the transmitter 102, and thus is not contained in the converted data, or serial message.

In cooperation with the description of Step #8 for the process of real-time definition and testing described above, FIGURES 14 and 15 illustrate an algorithm to effect the conversion from the stimulation images of the computer 128 to the composite bodily image for the transmitter 102.

Upon actuating the "log setting" screen button (Region 212 of FIGURE 9A; Step #8 of the process for real-time definition and testing), Step S100 initializes a database record in TESTRES and STIMMAP tables 78 and 82 (FIGURE 8). In Step S102, the user-set treatment parameter set is stored in portion 80 of TESTRES table 78. In Step S104, twenty image bytes, for each of the four display pages of the display 50, are initialized as Page1Bytes, Page2Bytes, Page3Bytes, Page4Bytes. Prior to the actual storage activities, the Area_Number variable is reset in Step S105

The first of several decisions for this algorithm is made at Step S106. In particular, a specific region (i.e., Region Area_Number) of the anterior stimulation image, from Region 210 of the computer 128 (also FIGURE 10), is analyzed to determine whether such region is highlighted. If the decision returns a "yes," the amplitude level for such region is stored in portion 86 of the STIMMAP table 82, and this region is subjected to a graphical conversion using the subroutine of FIGURE 15 (described in detail below).

Upon concluding Step S110 (or receiving a "no" decision from Step S106), a determination is made whether the corresponding region of the posterior stimulation image, from the computer 128 (FIGURE 10), is highlighted. If the decision returns a "yes," the amplitude level for such region is stored in portion 88 of the STIMMAP table 82, and this region is subjected to a graphical conversion also using the subroutine of FIGURE 15.

After conclusion of Step S116 (or receiving a "no" decision from Step S112), an inquiry is made whether the last region of both the stimulation images has been considered (Step S118). If not ("no" in Step S118), the Area_Number variable is increased by one (Step S122), and the routine returns to the decision of Step S106. Alternatively, if the last region has been considered ("yes" in Step S118), variables Page1Bytes, Page2Bytes, Page3Bytes, and Page4Bytes are stored in portion 84 of the STIMMAP table 82, and the routine is concluded.

In reference to the area conversion routine illustrated in FIGURE 15, a decision is initially made at Step S124 whether the originating call to the subroutine came from Step S110 or Step S116, or more particularly, whether the subject region derives from the anterior stimulation image or the posterior stimulation image. If "anterior," the conversion table of FIGURE 12 is referenced (Step S126), and alternatively, the conversion table of FIGURE 13 is referenced (Step S128).

In Step S130, after correlating the Area_Number variable and the values of Column 1 of the proper conversion table, values are extracted for the "Screen Display Page," "Left Side Column," "Left Bit Mask," "Right Side Column," and "Right Bit Mask." From the "Screen Display Page" value extracted in Step S130, the Page_Byte_List variable is equated to one of the Page1Bytes, Page2Bytes, Page3Bytes, and Page4Bytes variables in Step S132. In Step S134, the current byte value is extracted from the page defined by the Page_Byte_List variable. In this instance, the "Left Side Column" value is used as an index into the Page_Byte_List page. Step S136 effects a logical "ORing" of the extracted current byte value (from Step S134) and the "Left Bit Mask" value (from Step S130). The output of Step S136 is returned as the subject byte value to the Page_Byte_List page (Step S138).

In Step S140, the current byte value is extracted from the page defined by the Page_Byte_List variable using the "Right Side Column" value as an index into the Page_Byte_List page. Step S142 effects a logical "ORing" of the extracted current byte value (from Step S140) and the "Right Bit Mask" value (from Step S130). The output of Step S142 is returned as the subject byte value to the Page_Byte_List page (Step S144). The routine returns following these conversion steps.

Consistent with the description of the algorithm of FIGURE 15 and the illustration of FIGURE 10, it should be noted that the regional segmentation of both the anterior image and the posterior image is designed to produce regionally-compatible images. Specifically, the anterior image and the posterior image should maintain the same number of regions, and the regions should be consistently arranged so that like-numbered (i.e., like-identified) regions will effectively merge upon the symmetrical overlay of the anterior and posterior images.

For at least this example, the composite bodily image displayable on the display 50 is provided with a number of regions numerically consistent with one of either the anterior or the posterior stimulation images from the computer 128. It is contemplated, however, that this will not always be achievable, wherein the composite bodily image for the transmitter 102 will be required to display an abridged version of the image data of the stimulation images. To this end, the algorithm of FIGURE 15 would further be required to assess each region, and a number of adjacent region(s) (the number of adjacent regions being dependent upon the available resolution of the composite bodily graphic), for purposes of combining the graphical data of such regions for display in display 50.

While the above algorithm describes a graphical conversion process that occurs at the time of data storage, it should be appreciated that the timing for such conversion is not critical. Rather, the graphical conversion could instead occur at the time of downloading the stimulation settings and the program controls from the computer 128 to the transmitter 102.

Of further note, much of information conveyed here regarding the conversion algorithm is a function of the very specific display 50 chosen for the described embodiment.

Consequently, it should be noted that substantive information within the conversion tables (FIGURES 12 and 13), described means for addressing the display 50 (e.g., 1 byte instructions, coordinate addressing based on columns and pages, etc.), and the like serve only as one exemplary form of the present invention. The use of other displays could alter these particular aspects of the above disclosure; however, any such substitution would not be outside the scope of the disclosed invention.

**Therapy Definition**

Upon completing the definition and testing of various stimulation parameters, all of the recorded stimulation settings are displayed in, and are available for selection through, Region 216 of the screen shot of FIGURE 9B. Program, or therapy, creation is achieved by the following steps:

Step A: A program is selected from Region 226. Each program can be named using an alphanumeric designation (e.g., "sleeping," "sitting," "standing," etc.). Depending on the system, such alphanumeric designation may or may not be transferred to the transmitter 102. If transferred, such designation could be displayed in display 50. As but one example, such designation could be displayed in at least the program selection mode (FIGURES 7A-7D) to better assist a user in appreciating the intended purpose of each program in the event such purpose cannot be gleaned from the displayed composite graphic. As an alternative to displaying the designation, the transmitter 102 could store the designation in memory for later transfer to a newly connected computer 128 to provide additional information to a reviewing physician.

Step B: With a program selected, a number of stimulation settings can then be selected from Region 216. As stated above, for a most preferred embodiment, no more than eight stimulation settings can be attributed to any one program.

Step C: With the desired stimulation setting(s) selected, the "Add Stim Set(s) to Prog." screen button (Region 218) is actuated. Upon actuation, the software effects the following actions: (i) corresponding stimulation setting(s) is/are added to the selected program; (ii) entries corresponding to the transferred stimulation settings are

created in the STIMSET table 76, and links are established between such entries and the PROGRAMS table 74; and (iii) TESTRES and STIMMAP references are added to the new STIMSET records.

Step D: Upon completing the therapy definition, the "download programs" screen button (Region 222) can be actuated, and if so, the indicated programs, with related stimulation settings, are transferred to the connected transmitter 102.

During the download process, it is preferred that a status screen (FIGURE 9C) be provided to inform the user as to the progress of the download. At least in the illustrated embodiment, at Region 224, stimulation graphics corresponding to at least the individual stimulation settings are shown as they are downloaded. Although the creation of a program's composite graphic (FIGURE 5) can occur at any time after definition of the program, it is preferred that during the downloading process, the individual graphic regions of each stimulation settings are subject to a logical "ORing", and the result of such process is stored in the COMPOSITE GRAPHIC field of a program data file (FIGURE 4).

## General

While the above description focuses on the use of a general purpose computer (e.g., laptop or desktop systems), using conductive or alternative connection methods (e.g., infrared transmission, radio-frequency transmission, ultrasonic transmission, etc.), it should be appreciated that the "computer" of the present invention could equally be represented by a dedicated hand-held programmer or portable computing devices, e.g., Palm®-type devices, Windows™ CE-based devices, and the like.

Although this disclosure has concentrated its examples on RF stimulation systems, there is no limitation that would prevent this invention from being applied to implanted pulse generator (IPG) systems that offer multiple stimulation settings or therapy programs.

While the above description further focuses on the present invention being used in the context of spinal cord stimulation systems, it should be noted that the present invention is equally applicable to any application that experiences the frustrations identified above for

systems that store multiple applications without sufficient means to readily identify such applications. As but a few examples where the present invention might obviously benefit the current state of the art, deep brain stimulation (DBS), transcutaneous electrical nerve stimulation (TENS), pulsed electromagnetic stimulation (PEMS), biofeedback applications, and programmable drug delivery systems.

Although visual imagery is believed to impart the greatest understanding to a user in a limited-sized display, it is not beyond the scope of this invention that the displayed stimulation "graphic" consist of or include a textual description of the specific stimulation setting and/or program. Such textual description could be fully descriptive (e.g., "upper torso") or simply use abbreviations (e.g., "UT"). Moreover, the textual descriptions could be provided by the user at the time of defining and testing the stimulation parameters or at the time of assembling the various programs, or the computer could formulate such textual descriptions, from a listing of prescribed options, based on the data used to otherwise generate the transmitter-based graphics.

While the invention has been described herein relative to a number of particularized embodiments, it is understood that modifications of, and alternatives to, these embodiments, such modifications and alternatives realizing the advantages and benefits of this invention, will be apparent to those of ordinary skill in the art having reference to this specification and its drawings. It is contemplated that such modifications and alternatives are within the scope of this invention as subsequently claimed herein, and it is intended that the scope of this invention claimed herein be limited only by the broadest interpretation of the appended claims to which the inventors are legally entitled.

**WHAT IS CLAIMED IS:**

1. A neuromodulation therapy system, connectable to a general purpose computer, the system comprising:

at least one multi-electrode, implantable stimulation lead to effect delivery of electrical energy to proximately positioned tissue;

an implantable receiver, connectable to the at least one stimulation lead, to deliver electrical energy to the at least one stimulation lead, such electrical energy being defined by an instructional control signal; and

a transmitter to transmit instructional control signal(s) to the receiver, the transmitter including:

a memory adapted to store at least two programs, each program including a plurality of treatment parameter sets, each treatment parameter set including a plurality of variables that defines a particularized electrical energy;

a selector to effect a selection of a stored program; and

a controller to execute a selected program, wherein the controller selectively converts the variables of each treatment parameter set of the selected program to respective control signals for transmission to the receiver.

2. A neuromodulation therapy system in accordance with Claim 1, further comprising a transmitter display,

wherein each treatment parameter set includes identification information that is subject to display in the transmitter display.

3. A neuromodulation therapy system in accordance with Claim 2, wherein identification information is representative of a perceived stimulation effect corresponding to a related treatment parameter set.

4. A neuromodulation therapy system in accordance with Claim 3, wherein identification information is pictorial in form and is presented relative to an anatomical reference.

5. A neuromodulation therapy system in accordance with Claim 2, wherein each program includes program-specific identification information that is subject to display in the transmitter display.

6. A neuromodulation therapy system in accordance with Claim 5, wherein the program-specific identification information of a given program consists of a composition of the identification information of each of the treatment parameter sets within such program.

7. A neuromodulation therapy system in accordance with Claim 1, wherein a treatment parameter set defines an electrode polarity or off-state for each of the electrodes of the stimulation lead.

8. A neuromodulation therapy system in accordance with Claim 1, wherein a treatment parameter set specifies a signal waveform that defines, in part, the electrical energy delivered by the system.

9. A neuromodulation therapy system in accordance with Claim 1, wherein the controller sequentially executes each treatment parameter set within a selected program.

10. A neuromodulation therapy system in accordance with Claim 1, further comprising setting modification controls that enables (i) selection of a treatment parameter set and (ii) modification of a variable of the selected treatment parameter set.

11. A neuromodulation therapy system in accordance with Claim 1, further comprising a general purpose computer to generate anatomically-based images specifically depicting an effect of individual treatment parameter sets.

12. A neuromodulation therapy system in accordance with Claim 11, further comprising a transmitter display,

wherein each treatment parameter set includes identification information, representative of the anatomically-based images corresponding to that treatment parameter set, that is displayable in the transmitter display.

13. A neuromodulation therapy system having an instruction transmission device, a receiver, and a delivery instrument, connectable to the receiver, to effect delivery of a neuromodulation therapy to proximately positioned tissue, whereas the instruction transmission device is adapted to transmit control signals to the receiver to effect delivery of the neuromodulation therapy through the connected delivery instrument, the system further comprising:

a memory adapted to store at least two programs, each program including a plurality of instructions that individually characterize therapy-defining control signals;

a selector to effect a selection of a stored program; and

a controller to execute a selected program, wherein the controller converts an instruction of the selected program to corresponding control signals for transmission to the receiver.

14. A tissue stimulation system having a transmitter, a receiver for implantation within a patient, and at least one multi-electrode, implantable stimulation lead, electrically connectable to the receiver, whereas the transmitter is adapted to transmit stimulation data to the receiver, which effects delivery of electrical energy through the connected stimulation lead, such electrical energy being defined by stimulation setting(s), the system further comprising:

a memory adapted to store at least two programs, each program including a plurality of stimulation settings;

a selector to effect a selection of a stored program; and

a controller to execute a selected program, wherein the controller converts a stimulation setting of the selected program to stimulation data for transmission to the receiver.

15. A tissue stimulation system in accordance with Claim 14, further comprising a transmitter display,

wherein each stimulation setting includes setting-specific information that is subject to display in the transmitter display.

16. A tissue stimulation system in accordance with Claim 15, wherein setting-specific information is representative of a patient-perceived stimulation effect corresponding to a related stimulation setting.

17. A tissue stimulation system in accordance with Claim 15, wherein setting-specific information corresponds to a visual anatomical reference.

18. A tissue stimulation system in accordance with Claim 15, wherein each program includes program-specific information that is subject to display in the transmitter display.

19. A tissue stimulation system in accordance with Claim 18, wherein the program-specific information of a given program consists of a composition of the setting-specific information of each of the stimulation settings within such program.

20. A tissue stimulation system in accordance with Claim 14, wherein a stimulation setting defines an electrode polarity or off-state for each of the electrodes of the stimulation lead.

21. A tissue stimulation system in accordance with Claim 14, wherein a stimulation setting specifies a signal waveform that defines, in part, the electrical energy delivered by the system.

22. A tissue stimulation system in accordance with Claim 14, wherein the controller sequentially executes each stimulation setting within a selected program.

23. A tissue stimulation system in accordance with Claim 14, further comprising setting modification controls that enables (i) selection of a stimulation setting and (ii) modification of a defining attribute of a selected stimulation setting.

24. A tissue stimulation system in accordance with Claim 23, wherein the defining attribute is an amplitude value.

25. A tissue stimulation system in accordance with Claim 14, further comprising a general purpose computer, connectable to at least the transmitter, to define and to supply stimulation settings to the transmitter.

26. A tissue stimulation system in accordance with Claim 14, further comprising a general purpose computer, connectable to at least the transmitter, to define the programs and to supply the programs to the transmitter.

27. A tissue stimulation system in accordance with Claim 14, further comprising a general purpose computer, connectable to at least the transmitter, to generate anatomically-based images specifically depicting an effect of individual stimulation settings.

28. A tissue stimulation system in accordance with Claim 27, further comprising a transmitter display,

wherein each stimulation setting includes setting-specific information, representative of the anatomically-based images corresponding to such stimulation setting, that is displayable in the transmitter display.

29. For a neuromodulation system having a memory to store a plurality of independent instructions to effect an equal number of stimulation profiles, a method for providing an identifier to enable a visual recognition of a functionality of each instruction, the steps comprising:

creating an instruction data file, which includes a plurality of variables that operatively defines a therapeutic application, to effect a stimulation profile when executed;

executing the instruction data file;

generating a graphical anatomical representation that effectively depicts a perceived stimulation profile;

assessing the anatomical representation and generating a representative graphical image; and

modifying the instruction data file to include data corresponding to the representative graphical image.

30. A method in accordance with Claim 29, wherein the anatomical representation is comprised of a plurality of source images.

31. A method in accordance with Claim 30, wherein the anatomical representation consists of a posterior-related image and an anterior-related image.

32. A method in accordance with Claim 30, wherein the step of assessing the anatomical representation and generating the representative graphical image involves merging the plurality of source images into a single image.

33. A method in accordance with Claim 29, wherein the anatomical representation is formed by a plurality of regions.

34. A method in accordance with Claim 33, wherein the anatomical representation is comprised of a plurality of source images, and each source image is formed by a plurality of related regions.

35. A method in accordance with Claim 34, wherein the step of assessing the anatomical representation and generating the representative graphical image includes effectively merging the plurality of source images, on a region-by-region basis, into a single image.

36. A method in accordance with Claim 34, wherein the step of assessing the anatomical representation and generating the representative graphical image includes effectively merging the plurality of images, on a region-by-region basis, into a single image having fewer regions than a source image of the anatomical representation.

37. For a neuromodulation system having a storage structure to store a plurality of independent settings to effect an equal number of stimulation profiles, a memory device including stored instructions, executable by a computer, the instructions enabling a method for providing an identifier to facilitate a visual recognition of a functionality of each setting, the method comprising the steps of:

creating a setting data file, which includes a plurality of variables that operatively defines a neuromodulation application, to effect a stimulation profile when executed;

executing the setting data file;

generating an anatomical representation that embodies a patient-perceived stimulation profile;

assessing the anatomical representation and generating a representative graphical image; and

modifying the setting data file to include data corresponding to the representative graphical image.

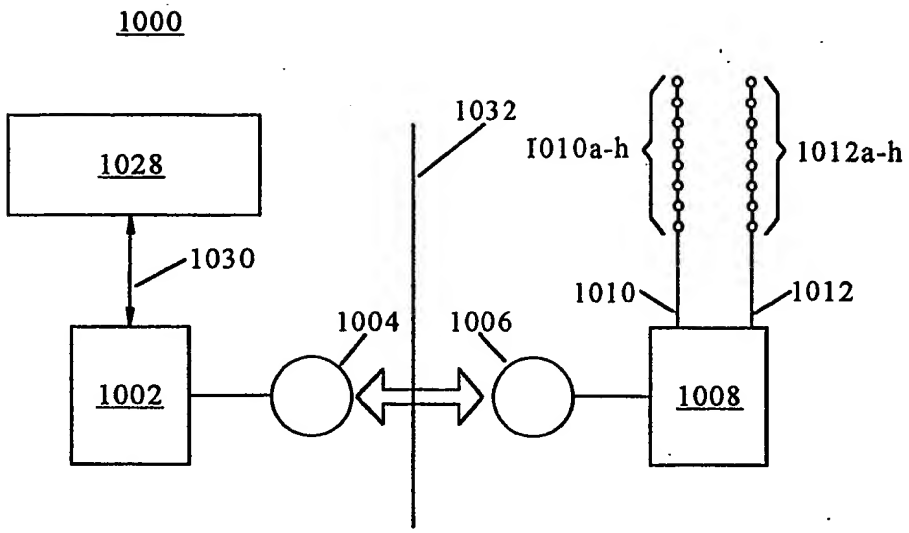



*FIG. 1*

***Prior Art***

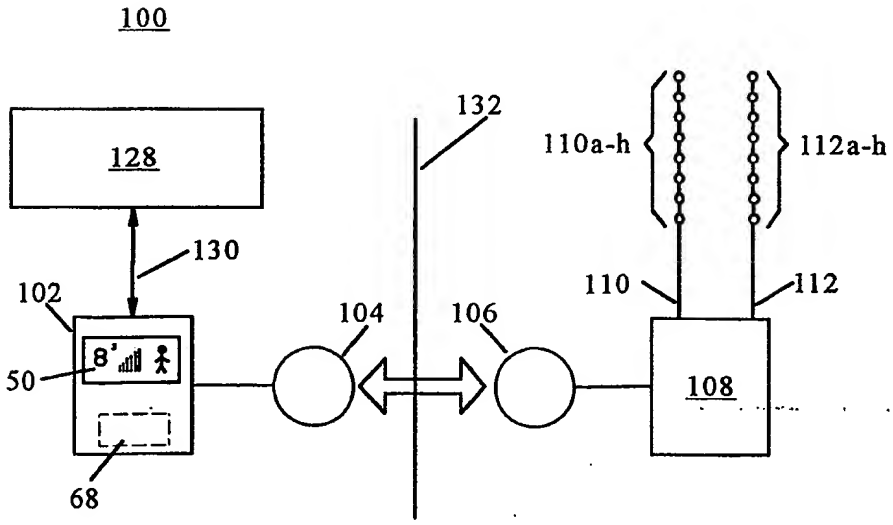



*FIG. 2*

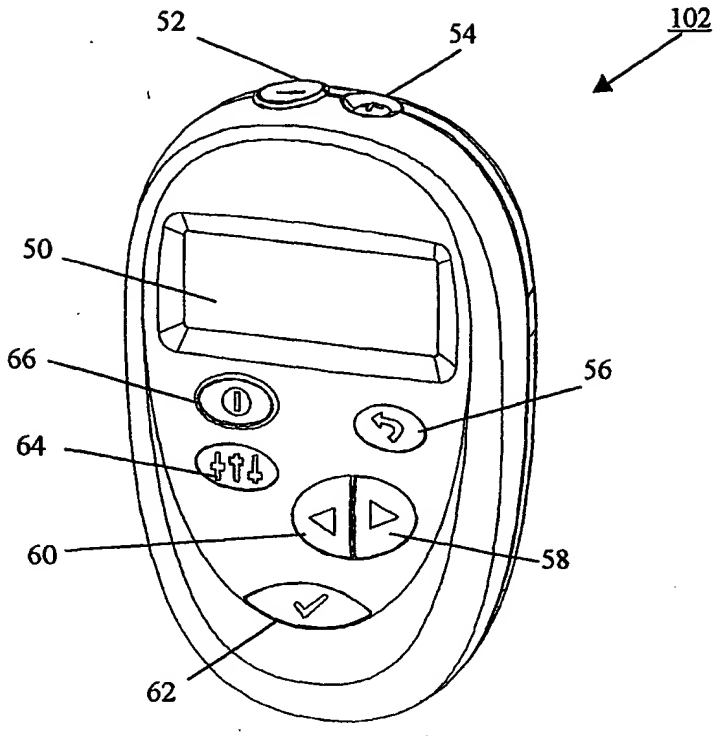

52
54
102
50
66
56
64
60
58
62

*FIG. 3*

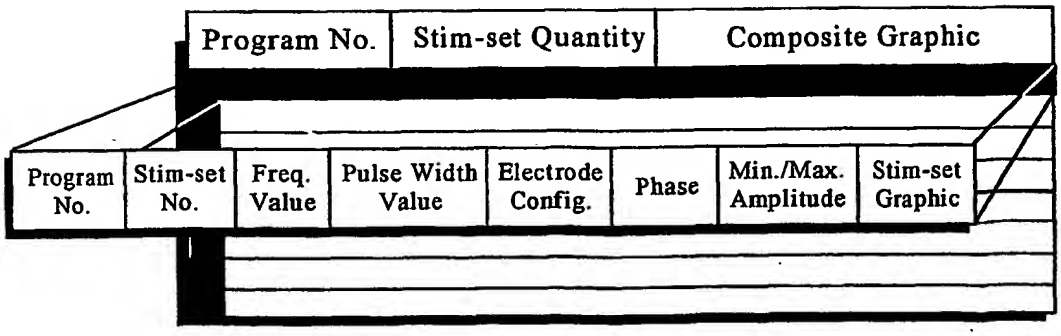

Program No.
Stim-set Quantity
Composite Graphic
Program No.
Stim-set No.
Freq. Value
Pulse Width Value
Electrode Config.
Phase
Min./Max. Amplitude
Stim-set Graphic

*FIG. 4*

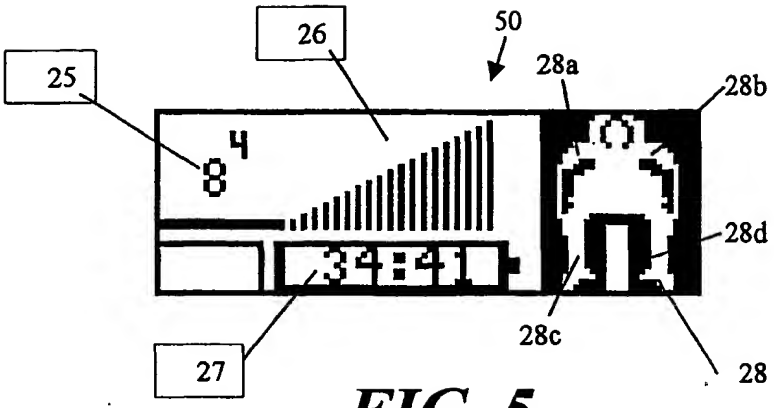



FIG. 5

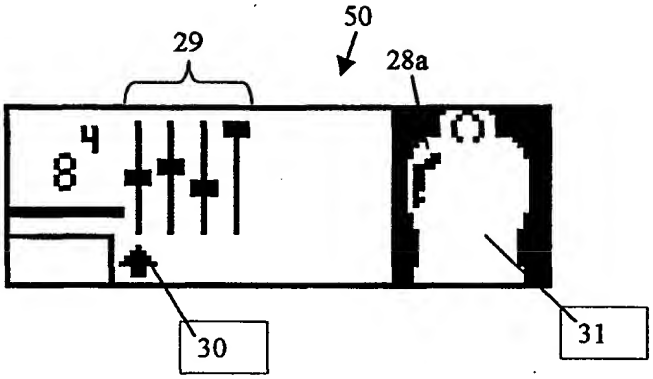



FIG. 6

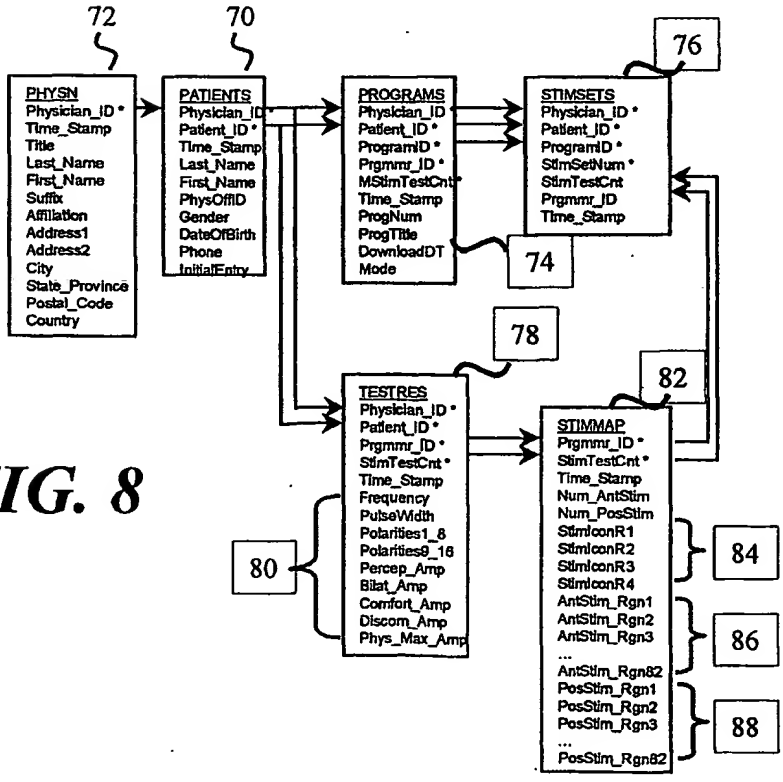



FIG. 8

FIG. 7A

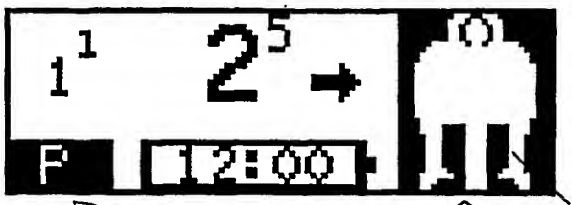




FIG. 7B

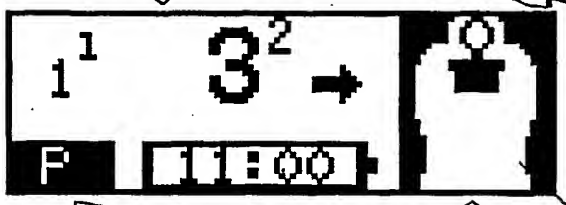




FIG. 7C

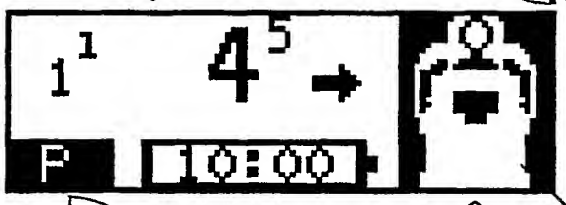
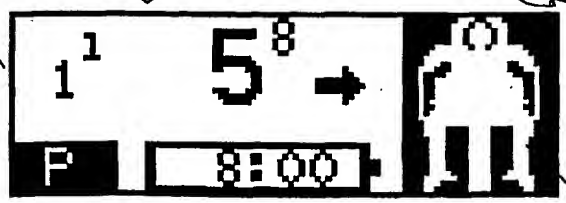




FIG. 7D



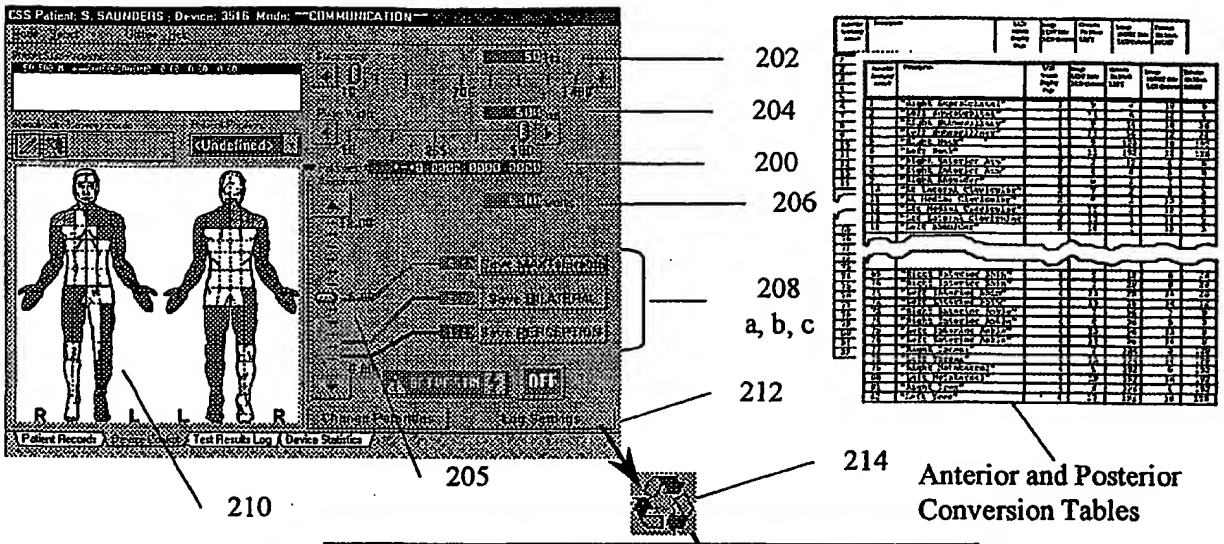



FIG. 9A

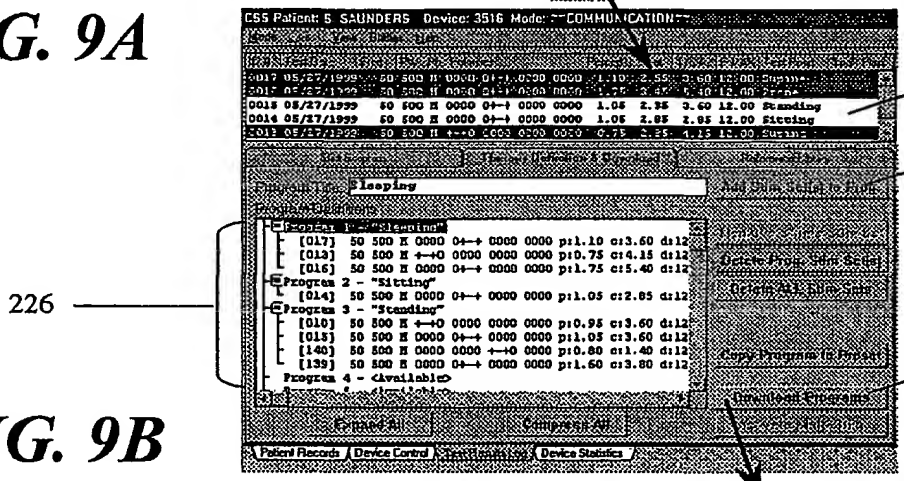



FIG. 9B

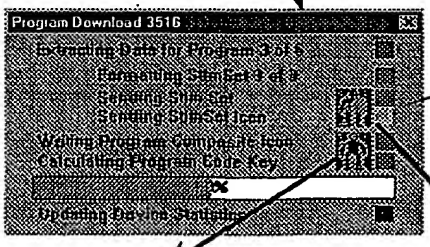



FIG. 9C


FIG. 9D

FIG. 9E

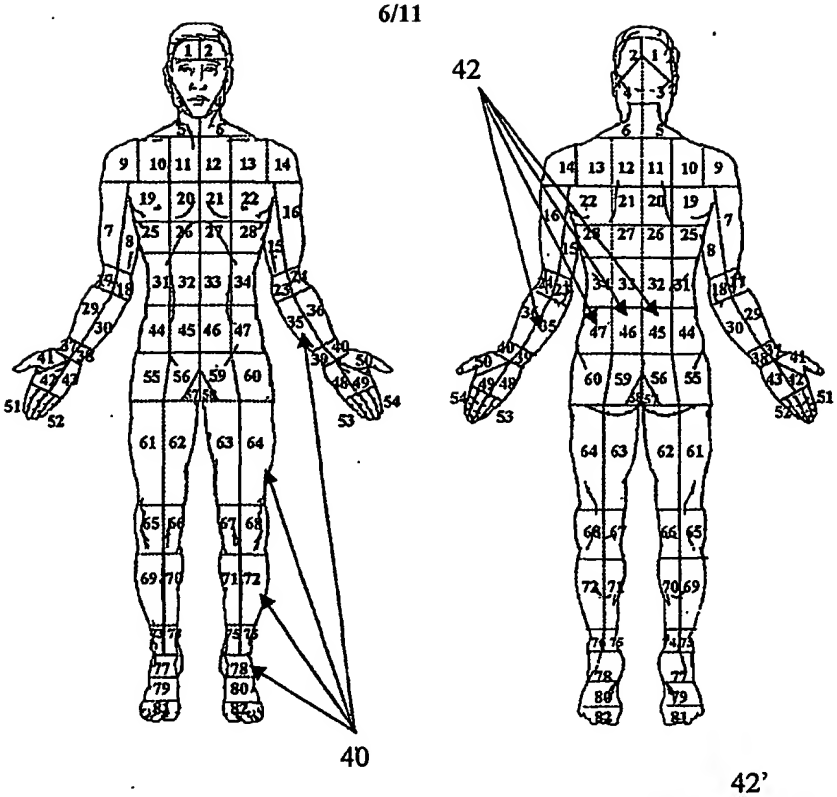



FIG. 10

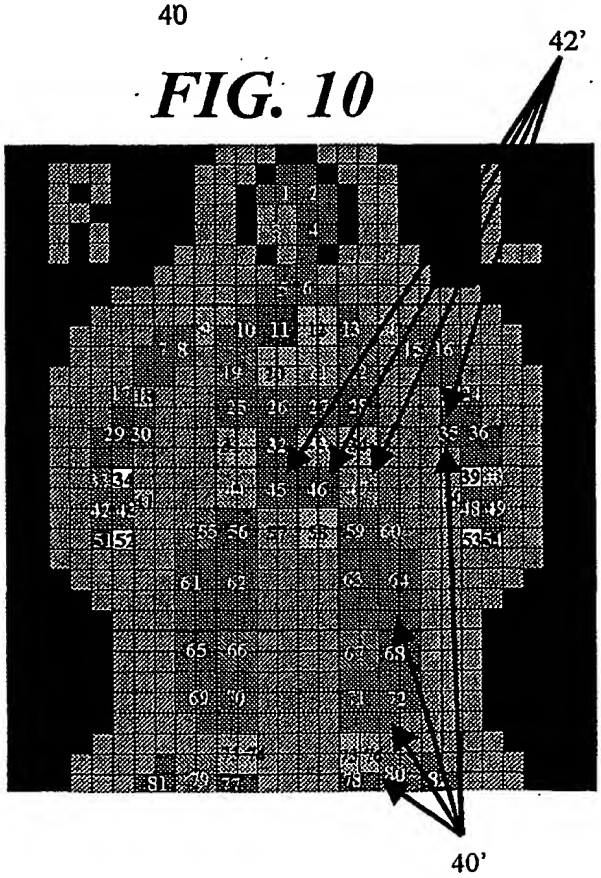



FIG. 11

| Anterior Anatomy Area # | Description | LCD Screen Display Page | Image LEFT Side LCD Column | Column Bit Mask LEFT | Image RIGHT Side LCD Column | Column Bit Mask RIGHT |
|---|---|---|---|---|---|---|
| 1 | Right SupraOrbital | 1 | 9 | 4 | 10 | 6 |
| 2 | Left SupraOrbital | 1 | 11 | 6 | 12 | 4 |
| 3 | Right Submaxillary | 1 | 9 | 24 | 10 | 56 |
| 4 | Left Submaxillary | 1 | 11 | 56 | 12 | 24 |
| 5 | Right Neck | 1 | 9 | 128 | 10 | 192 |
| 6 | Left Neck | 1 | 11 | 192 | 12 | 128 |
| 7 | Right Exterior Arm | 2 | 3 | 12 | 4 | 6 |
| 8 | Right Interior Arm | 2 | 4 | 8 | 5 | 6 |
| 9 | Right Shoulder | 2 | 6 | 3 | 7 | 1 |
| 10 | Right Lateral Clavicular | 2 | 7 | 2 | 8 | 3 |
| 11 | Right Medial Clavicular | 2 | 9 | 3 | 10 | 3 |
| 12 | Left Medial Clavicular | 2 | 11 | 3 | 12 | 3 |
| 13 | Left Lateral Clavicular | 2 | 13 | 3 | 14 | 2 |
| 14 | Left Shoulder | 2 | 14 | 1 | 15 | 3 |
| 15 | Left Interior Arm | 2 | 16 | 6 | 17 | 8 |
| 16 | Left Exterior Arm | 2 | 17 | 6 | 18 | 12 |
| 17 | Right Exterior Elbow | 2 | 2 | 16 | 2 | 0 |
| 18 | Right Interior Elbow | 2 | 3 | 16 | 3 | 0 |
| 19 | Right Lateral Mammary | 2 | 7 | 12 | 8 | 12 |
| 20 | Right Medial Mammary | 2 | 9 | 12 | 10 | 12 |
| . | . | . | . | . | . | . |
| . | . | . | . | . | . | . |
| . | . | . | . | . | . | . |
| 48 | Left Ulnar Palm | 3 | 20 | 6 | 20 | 0 |
| 49 | Left Median Palm | 3 | 19 | 6 | 19 | 0 |
| 50 | Left Thumb | 3 | 18 | 2 | 18 | 0 |
| 51 | Right Median Fingers | 3 | 2 | 8 | 2 | 0 |
| 52 | Right Ulnar Fingers | 3 | 1 | 8 | 1 | 0 |
| 53 | Left Ulnar Fingers | 3 | 20 | 8 | 20 | 0 |
| 54 | Left Median Fingers | 3 | 19 | 8 | 19 | 0 |
| 55 | Right Hip | 3 | 5 | 8 | 6 | 12 |
| 56 | Right Pubic | 3 | 7 | 12 | 8 | 12 |
| 57 | Right Perineum | 3 | 9 | 12 | 10 | 12 |
| 58 | Left Perineum | 3 | 11 | 12 | 12 | 12 |
| 59 | Left Pubic | 3 | 13 | 12 | 14 | 12 |
| 60 | Left Hip | 3 | 15 | 12 | 16 | 8 |
| 61 | Right Exterior Thigh | 3 | 5 | 240 | 6 | 240 |
| 62 | Right Interior Thigh | 3 | 7 | 240 | 8 | 240 |
| . | . | . | . | . | . | . |
| . | . | . | . | . | . | . |
| . | . | . | . | . | . | . |
| 73 | Right Exterior Ankle | 4 | 7 | 96 | 7 | 0 |
| 74 | Right Interior Ankle | 4 | 8 | 96 | 8 | 0 |
| 75 | Left Interior Ankle | 4 | 13 | 96 | 13 | 0 |
| 76 | Left Exterior Ankle | 4 | 14 | 96 | 14 | 0 |
| 77 | Right Tarsal | 4 | 7 | 128 | 8 | 128 |
| 78 | Left Tarsal | 4 | 13 | 128 | 14 | 128 |
| 79 | Right Metatarsal | 4 | 5 | 192 | 6 | 192 |
| 80 | Left Metatarsal | 4 | 15 | 192 | 16 | 192 |
| 81 | Right Toes | 4 | 3 | 128 | 4 | 192 |
| 82 | Left Toes | 4 | 17 | 192 | 18 | 128 |

*FIG. 12*

| Posterior Anatomy Area # | Description | LCD Screen Display Page | Image LEFT Side LCD Column | Column Bit Mask LEFT | Image RIGHT Side LCD Column | Column Bit Mask RIGHT |
|---|---|---|---|---|---|---|
| 1 | Right Parietal | 1 | 9 | 4 | 10 | 6 |
| 2 | Left Parietal | 1 | 11 | 6 | 12 | 4 |
| 3 | Right Occipital | 1 | 9 | 24 | 10 | 56 |
| 4 | Left Occipital | 1 | 11 | 56 | 12 | 24 |
| 5 | Right Neck | 1 | 9 | 128 | 10 | 192 |
| 6 | Left Neck | 1 | 11 | 192 | 12 | 128 |
| 7 | Right Exterior Arm | 2 | 3 | 12 | 4 | 6 |
| 8 | Right Interior Arm | 2 | 4 | 8 | 5 | 6 |
| . | | | | | | |
| . | | | | | | |
| . | | | | | | |
| 21 | Left Interscapular | 2 | 11 | 12 | 12 | 12 |
| 22 | Left Scapular | 2 | 13 | 12 | 14 | 12 |
| 23 | Left Interior Elbow | 2 | 18 | 16 | 18 | 0 |
| 24 | Left Exterior Elbow | 2 | 19 | 16 | 19 | 0 |
| 25 | Right Infrascapular | 2 | 7 | 48 | 8 | 48 |
| 26 | Left Midback | 2 | 9 | 48 | 10 | 48 |
| 27 | Right Midback | 2 | 11 | 48 | 12 | 48 |
| 28 | Left Infrascapular | 2 | 13 | 48 | 14 | 48 |
| 29 | Right Exterior Forearm | 2 | 1 | 192 | 2 | 96 |
| 30 | Right Interior Forearm | 2 | 2 | 128 | 3 | 96 |
| 31 | Right Lateral Lumbar | 2 | 7 | 192 | 8 | 192 |
| 32 | Right Medial Lumbar | 2 | 9 | 192 | 10 | 192 |
| 33 | Left Medial Lumbar | 2 | 11 | 192 | 12 | 192 |
| 34 | Left Lateral Lumbar | 2 | 13 | 192 | 14 | 192 |
| 35 | Left Interior Forearm | 2 | 18 | 96 | 19 | 128 |
| 36 | Left Exterior Forearm | 2 | 19 | 96 | 20 | 192 |
| 37 | Right Exterior Wrist | 3 | 1 | 1 | 1 | 0 |
| 38 | Right Interior Wrist | 3 | 2 | 1 | 2 | 0 |
| 39 | Left Interior Wrist | 3 | 19 | 1 | 19 | 0 |
| 40 | Left Exterior Wrist | 3 | 20 | 1 | 20 | 0 |
| 41 | Right Thumb | 3 | 3 | 2 | 3 | 0 |
| 42 | Right Median Palm | 3 | 2 | 6 | 2 | 0 |
| 43 | Right Ulnar Palm | 3 | 1 | 6 | 1 | 0 |
| 44 | Right Coxal | 3 | 7 | 3 | 8 | 3 |
| 45 | Right Low Back | 3 | 9 | 3 | 10 | 3 |
| 46 | Left Low Back | 3 | 11 | 3 | 12 | 3 |
| 47 | Left Coxal | 3 | 13 | 3 | 14 | 3 |
| . | | | | | | |
| . | | | | | | |
| . | | | | | | |
| 63 | Left Interior Thigh | 3 | 13 | 240 | 14 | 240 |
| 64 | Left Exterior Thigh | 3 | 15 | 240 | 16 | 240 |
| 65 | Right Exterior Knee | 4 | 5 | 3 | 6 | 3 |
| 66 | Right Interior Knee | 4 | 7 | 3 | 8 | 3 |
| 67 | Left Interior Knee | 4 | 13 | 3 | 14 | 3 |
| 68 | Left Exterior Knee | 4 | 15 | 3 | 16 | 3 |
| 69 | Right Exterior Claif | 4 | 5 | 12 | 6 | 28 |
| 70 | Right Interior Calf | 4 | 7 | 28 | 8 | 28 |
| 71 | Left Interior Calf | 4 | 13 | 28 | 14 | 28 |
| 72 | Left Exterior Calf | 4 | 15 | 28 | 16 | 12 |
| . | | | | | | |
| . | | | | | | |
| . | | | | | | |
| 82 | Left Toes | 4 | 17 | 192 | 18 | 128 |

*FIG. 13*

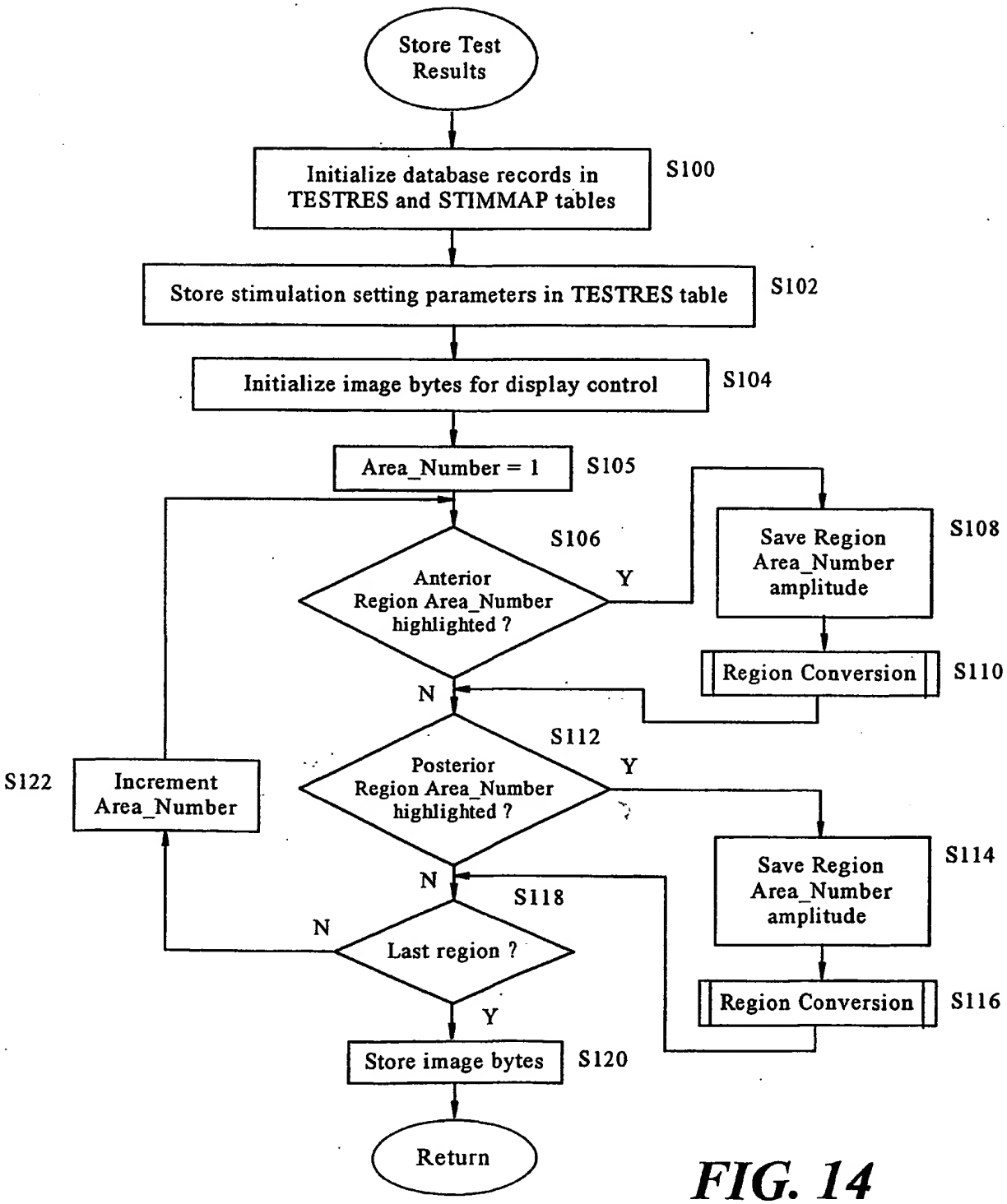

Store Test Results
Initialize database records in TESTRES and STIMMAP tables
S100
Store stimulation setting parameters in TESTRES table
S102
Initialize image bytes for display control
S104
Area_Number = 1
S105
S106
Anterior Region Area_Number highlighted ?
Y
N
Save Region Area_Number amplitude
S108
Region Conversion
S110
S112
Posterior Region Area_Number highlighted ?
Y
N
Save Region Area_Number amplitude
S114
Region Conversion
S116
S118
Last region ?
N
Y
S122
Increment Area_Number
Store image bytes
S120
Return

*FIG. 14*

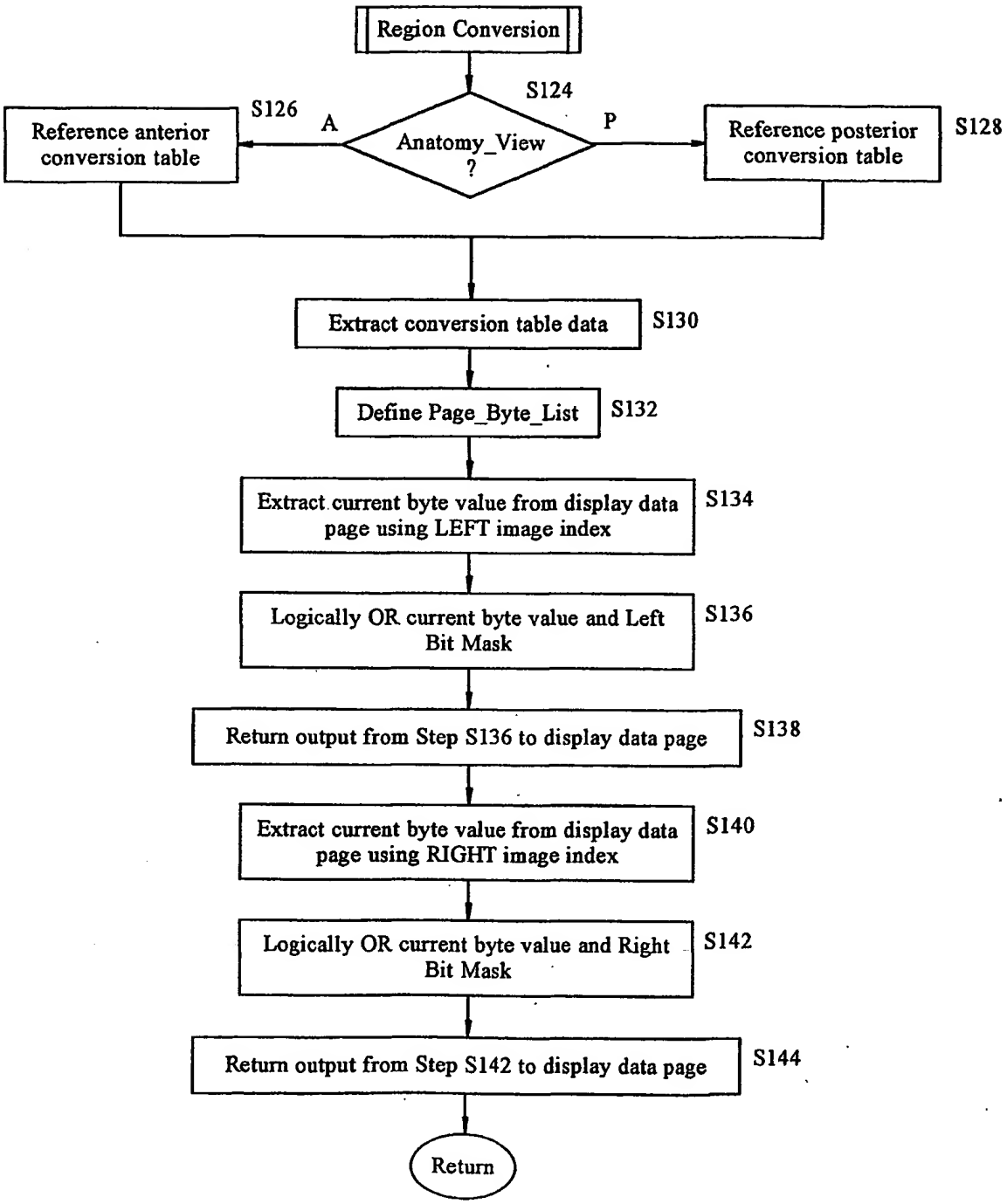

Region Conversion
S124
S126
A
Anatomy_View ?
P
S128
Reference anterior conversion table
Reference posterior conversion table
Extract conversion table data
S130
Define Page_Byte_List
S132
Extract current byte value from display data page using LEFT image index
S134
Logically OR current byte value and Left Bit Mask
S136
Return output from Step S136 to display data page
S138
Extract current byte value from display data page using RIGHT image index
S140
Logically OR current byte value and Right Bit Mask
S142
Return output from Step S142 to display data page
S144
Return

*FIG. 15*

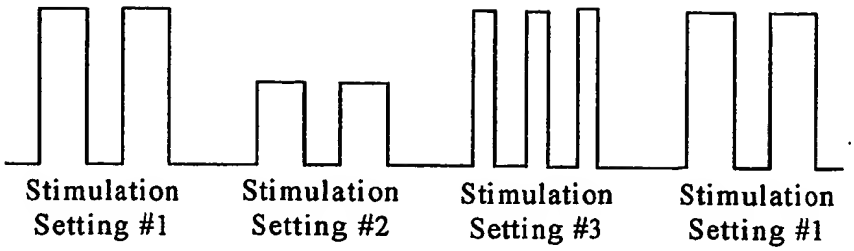



*FIG. 16A*

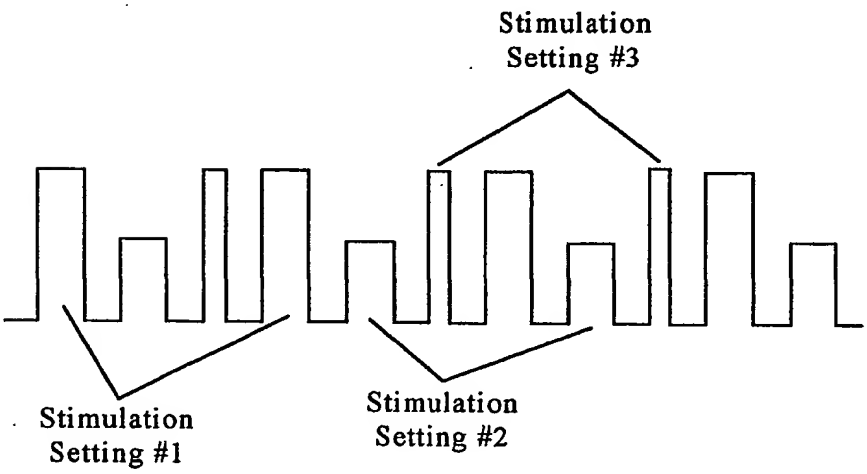



*FIG. 16B*

# INTERNATIONAL SEARCH REPORT

Inte inal Application No
PCT/US 01/18119

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/34 A61N1/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | EP 0 811 395 A (QUEST MEDICAL INC) 10 December 1997 (1997-12-10) | 1,7-10, 13-15, 18,20-22 |
| A | page 4, column 5, line 8 -page 6, column 9, line 25; claims; figures | 2,11,19, 23-26, 29,37 |
| X | US 5 938 690 A (VAN CAMPEN GEORGE ET AL) 17 August 1999 (1999-08-17) cited in the application | 1,13,14, 29,37 |
| A | column 10, line 38 -column 14, line 44; claims; figures | 2-12, 15-29,37 |

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 5 October 2001 | 12/10/2001 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Rakotondrajaona, C |

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# INTERNATIONAL SEARCH REPORT

Inte nal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 5 443 486 A (HRDLICKA GREGORY A ET AL)<br>22 August 1995 (1995-08-22)<br><br>column 5, line 4 -column 9, line 2;<br>figures | 1,9,10,<br>13,14,<br>22-26,<br>29,37 |
| A | US 5 370 672 A (FOWLER KIM R ET AL)<br>6 December 1994 (1994-12-06)<br><br>column 6, line 9 -column 8, line 63;<br>figures | 1-9,<br>13-17,<br>20-26,<br>29-31,37 |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter ıal Application No
PCT/US 01/18119

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| | | EP 0811395 A2 | 10-12-1997 |
| US 5938690 A | 17-08-1999 | EP 0811395 A2 | 10-12-1997 |
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| | | CA 2199958 A1 | 04-04-1996 |
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| | | JP 2823960 B2 | 11-11-1998 |
| | | JP 9511431 T | 18-11-1997 |
| | | WO 9609852 A1 | 04-04-1996 |
| US 5370672 A | 06-12-1994 | NONE | |